

REMARKS

Upon entry of the foregoing listing of claims, claims 1, 29, and 34-41 have been amended, claims 28 and 30-33 have been canceled, while claims 2-27 remain canceled. Thus claims 1, 29, and 34-41 are currently pending. The amendment to claim 1 has been made to address the 35 U.S.C. § 112, first paragraph rejections. Support of the various type of cancers recited in claim 1 can be found throughout the specification and more specifically, for example, in previous claim 28. Applicants note that the amendment to claim 1 has been made to advance prosecution and without acquiescence to the rejections raised in the Final Office Action. Applicants reserve the right to prosecute the removed subject matter in one or more continuation or divisional applications. The amendments to claims 29 and 34-41 have been made to correct minor typographical errors and have not been made to overcome the prior art, and thus, should be considered to have been made for a purpose unrelated to patentability, and no estoppel should be deemed to attach thereto. These amendments do not add prohibited new matter and are fully supported by the specification.

**Formal Matters**

Applicants note that the cover page of the Office Action indicates that the Action is Final. However, there is no indication in the body of the Action that Finality is intended. Applicants also note that the Patent Office Application Information Retrieval (PAIR) system indicates that the action is non-final. In view of the new art-based rejections, apparently not necessitated by Applicants' amendments, the lack of indication

of Finality in the body of the action, and the PAIR status, Applicants assume that finality was not intended, and treat this amendment as a response to a non-final action.

### **Claim Rejections under 35 U.S.C. 112, first paragraph**

The Office Action maintains the rejection of claims 1, 28-29, and 32-41 under 35 U.S.C. § 112, first paragraph, for allegedly failing to comply with the enablement requirement. The Examiner asserts that the specification does not reasonably provide enablement for methods of completely inhibiting or completely preventing any and all cancer cell growth or any solvates or hydrates of compound of formula I.

Applicants respectfully request withdrawal of the § 112 rejections. Applicants initially note that claim 1 recites “[a] method for therapeutic treatment of” cancers, not “a method for completely inhibiting . . . any and all cancer cell growth” as construed by the Office. Applicants respectfully submit that the specification, at least in Test Examples 1-6 and in Figures 1-4, enables the claimed method for therapeutic treatment. More specifically, Applicants respectfully direct the Examiner’s attention to Test Example 2 and Figures 1-4, which disclose the reduction of melanoma, fibrosarcoma, neuroblastoma, and breast cancer cells in dependence of the concentration and time of treatment with elected compound No. 4. Applicants note that it is this reduction of cancer cells upon treatment with the elected compounds that provides support of the claimed method.

Furthermore, Applicants respectfully submit that it is very well known in the art that a successful cancer treatment does not require a complete inhibition of any and all cancer growth. Applicants submit that a reduction of the growth rate of a cancer is already an successful treatment as it permits the person of ordinary skill to control the fast

and often malignant division of cancer cells. Therefore, Applicants submit that a complete inhibition is not a requirement for a successful treatment.

Accordingly, the specification provides sufficient enablement to one of ordinary skill to practice the claimed invention, i.e., one of ordinary skill in the art would understand the specification with respect to reducing cancer cell growth and recognize that the compounds disclosed in the specification are useful for a method of therapeutic treatment of various types of cancers. Therefore, Applicants respectfully submit that in view of the amendment to claim 1 and these remarks, the claims are fully enabled by the specification, and respectfully request withdrawal of the § 112 rejections.

Applicants maintain that the disclosures of the specification fully support and enable the presently claimed invention. Applicants respectfully note that the Patent Office bears the burden of rebutting Applicants' statements that the specification fully enables the presently claimed invention. That is, if the Patent Office believes that "therapeutic treatment" requires complete inhibition and complete prevention of any and all cancer growth, the Office must substantiate those assertions. Absent such support, the rejections must be withdrawn.

The Office Action also rejects claims 1, 28-29, and 32-41 under 35 U.S.C. § 112, first paragraph, for allegedly failing to enable the phrase "and a hydrate thereof and a solvate thereof." Applicants respectfully request withdrawal of this rejection in view of Applicants' canceling of the subject matter in claim 1 pertaining to the hydrates and solvates.

**Claim Rejections under 35 U.S.C. § 103(a)**

The Office Action rejects claims 1, 28-29, and 32-41 under 35 U.S.C. § 103(a) as allegedly unpatentable over U.S. Patent No. 3,906,034 to Franz et al., in view of U.S. Patent No. 6,492,425 Callahan et al. The Action appears to argue that it would have been obvious to use compounds similar to those disclosed in Franz et al. in the methods disclosed in Callahan et al. Applicants respectfully submit that the claimed invention is not obvious in view of the cited art.

Applicants note that Callahan et al. teaches that its compounds have inhibitory action against NF- $\kappa$ B and proliferation of tumor cells, and have antitumor action. Franz et al., on the other hand, is directed solely to compounds having anthelmintic action, which is completely unrelated to the actions discussed in Callahan et al. Moreover, Franz et al. fails to make any mention of the treatment of any indication recited in Applicants' present claims, or even the mention of the treatment of any indication mentioned in Callahan et al. Applicants respectfully submit that a person skilled in the art would not have used the compounds of Franz et al. in the methods of Callahan et al. with any expectation of achieving NF- $\kappa$ B inhibition or inhibitory action against tumor cells. Applicants respectfully submit that there is no reason a person of skill in the art would combine these teachings, and even if combined, there would be no expectation of success.

Applicants also respectfully note that Callahan et al. teaches that R<sub>B</sub> may be C<sub>1-6</sub> alkyl (column 3, lines 37-40) and also teaches that the C<sub>1-6</sub> alkyl may be substituted with one or two halogen atoms (column 4, lines 38-44). However, Callahan et al. does not teach that the compounds may be substituted with three or more halogens, despite the fact that CF<sub>3</sub> and similar substituents were known in the medicinal chemistry art. Applicants

respectfully submit that a person of skill in the art would read the above-cited teaching as being especially noteworthy – expressly excluding CF<sub>3</sub>. Thus, Applicants respectfully submit that a person of ordinary skill in the art would not combine Franz et al.’s teachings of CF<sub>3</sub>-substituted compounds with those of Callahan et al., which expressly exclude CF<sub>3</sub>. For at least this reason as well, Applicants submit that the obviousness rejection should be withdrawn.

#### **Nonstatutory Obviousness-Type Double-Patenting**

The Office Action provisionally rejects claims 1, 18-24, and 28-29 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 17, 21, 24-33 of copending U.S. Patent Application No. 10/546,407 and further in view of Callahan et al.

The Office Action provisionally rejects claims 1, 28-29, 32-41 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 13-14, 19-23, 25-30, 55-63 of copending U.S. Patent Application No. 10/433,619 and further in view of Callahan et al.

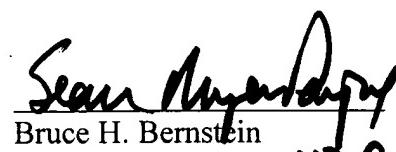
Applicants respectfully request that these provisional obviousness-type double patenting rejection be held in abeyance until the Examiner has indicated allowable subject matter in the present application and allowable subject matter has also been indicated in the co-pending application. Without knowing which claims in the present application and which claims in the co-pending application will be allowed, Applicants are unable to determine if the filing of a terminal disclaimer is necessary.

CONCLUSION

For the reasons discussed above, it is respectfully submitted that the rejections be withdrawn. Favorable consideration with early allowance of all of the pending claims is most earnestly requested.

If there are any comments or questions, the undersigned may be contacted at the below-listed telephone number.

Respectfully submitted,  
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